## IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OKLAHOMA

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In re: Genentech, Inc., Herceptin	)	MDL Docket No. 16-MD-2700
(Trastuzumab) Marketing and Sales	)	
Practices Litigation	)	Document Relates to:
	)	All Cases
	)	

# GENENTECH, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL GENENTECH TO COMPLY WITH THE COURT'S JUNE 16, 2017 ORDER

Genentech has acted in good faith and complied with the Court's instructions in the May 8, 2017 Opinion and Order (the "May 8 Order) (Dkt. 207) and related June 16, 2017 Order (the "June 16 Order") (Dkt. 227) regarding identification of current and former employees by:

- Providing the list of more than 50 current and former employees referred to by Genentech's counsel in August 2016;
- Producing more than 2,600 pages of organizational chart records potentially referring to employees that may have been involved in the production or labeling of Herceptin; and
- Identifying the current employees and former employees determined to be those most likely to have relevant information regarding Plaintiffs' October 2015 Interrogatory Nos. 2(c) and (d), 10, and June 2016 Interrogatory No. 11.

Because it complied with each provision of the June 16 Order by July 6, there was no need for Genentech to file an affidavit detailing its efforts to comply with that Order. Plaintiffs' motion to compel further identification of current and former employees and the filing of an affidavit explaining Genentech's compliance efforts is unwarranted, and Genentech respectfully submits that the motion should be denied in its entirety.

#### I. RELEVANT BACKGROUND

A wide range of pre-emption-related discovery is currently underway in this matter, <sup>1</sup> and the parties are meeting and conferring on a scheduled (weekly) basis in furtherance of that discovery. Plaintiffs' motion takes issue with only a very narrow slice of that discovery—and specifically a handful of Genentech's interrogatory responses. The motion to compel is directed exclusively to Genentech's identification of current and former employees most likely to have relevant knowledge concerning the subjects indicated in Plaintiffs' Interrogatory Nos. 2(c), 2(d), 10, and 11. The motion challenges whether Genentech has complied with this Court's June 16 Order, which was issued in response to the Parties' Second Joint Submission Regarding Preemption Discovery ("SJS"), (Dkt. 223). The June 16 Order reflects a reinforcement and acceleration of Genentech's obligations under the May 8 Order to provide information in response to the interrogatories at issue. (See Dkt. 277.)

Because the Court's assessment of Genentech's compliance with the June 16 Order necessarily depends on the Court's earlier resolution of disputes over the scope of the interrogatories at issue as indicated in the May 8 Order, a brief review of the interlocking events that have led the parties to this point is warranted.

### A. Events Leading to the May 8 Order

Case Management Order #1 limited Phase I of discovery to the issues related to federal preemption (Dkt. 39). This substantive limitation gave rise to a number of discovery disputes ultimately detailed in the Parties' [First] Joint Submission Regarding Preemption Discovery ("FJS") (Doc 130). Genentech's obligation to supplement its responses to pending discovery

<sup>&</sup>lt;sup>1</sup> Phase I discovery efforts currently underway include Genentech's ongoing document collection, review, and production of both custodial and non-custodial documents, preparation for fact witness depositions expected to begin next week, and continuing negotiation of jointly-agreeable search terms.

requests was expressly stayed while Magistrate Judge Wilson conducted hearings and prepared to address the disputes described in the FJS. *See* Aug. 26, 2016 Hrg. Tr. at 7:15-17 ("And I think I was pretty clear last time that I don't want Genentech at this point to go about the process of actually gathering it"); 15:4-11. In its March 28, 2017 Order, this Court acknowledged the complexities that had already become evident during Phase I discovery, and announced its intention to extend Phase I to allow for the resolution of pending discovery disputes and completion of all necessary discovery (Doc. 187). Case Management Order #2 was entered immediately thereafter, and set the current close of preemption-related discovery for September 22, 2017 (Dkt. 188).

#### B. The May 8 Order

Following Magistrate Judge Wilson's resignation on April 17, 2017, this Court took up and resolved all pending discovery disputes with its May 8 Order (Dkt. 207). The dispute regarding Plaintiffs' "Interrogatories Seeking Identity of Individuals" (described at section VII of the FJS, Dkt. 130) was addressed by the May 8 Order as follows:

<u>Plaintiffs' Interrogatory No. 2(c)</u> asked Genentech to "[i]dentify each person who was employed by, affiliated with or acting in an agent capacity for Genentech and has knowledge regarding the following matters: . . . (c) The Herceptin label and Prescribing Information. The Court modified the scope of the interrogatory and ordered Genentech to "identify all current employees and the two former employees who are most likely to have relevant information" concerning the subject matter of the Interrogatory. (Dkt. 207 at 14.)

<u>Plaintiffs' Interrogatory No. 2(d)</u> also asked Genentech to "[i]dentify each person who was employed by, affiliated with or acting in an agent capacity for Genentech and has knowledge regarding the following matters: . . . (d) The FDA approval of Herceptin, its label, and its Prescribing Information. Again, the Court modified the scope of the interrogatory, and ordered Genentech to "make efforts to identify all current employees and the two former employees who are most likely to have relevant information" concerning the subject matter of the Interrogatory. (*Id.*)

<u>Plaintiffs' Interrogatory No. 10</u> asked Genentech to [i]dentify all persons who helped prepare each change to the Herceptin label and Prescribing Information

identified in response to Interrogatory No. 9. Once again, rather that requiring identification of all persons, the Court narrowed the scope of the interrogatory and instead ordered Genentech to "make efforts to identify all current employees and the two former employees who are most likely to have relevant information" concerning the subject matter of the Interrogatory. (Id.)

<u>Plaintiffs' Interrogatory No. 11</u> asked Genentech to "[i]dentify all persons and/or entities who have determined the concentration of the reconstituted Herceptin solution in any vial of the drug." Consistent with its treatment of the previous three disputed Interrogatories seeking identification of *all* persons, the Court again *narrowed the scope of the interrogatory* and ordered Genentech to "make efforts to identify all current employees and the two former employees who are most likely to have relevant information" concerning the subject matter of the Interrogatory. (*Id.*)

The Court further indicated in the May 8 Order that: (1) it was "limit[ing] the number of former employees to two in order to avoid an overly-burdensome inquiry for Defendant," and (2) Genentech was to "focus its efforts on identifying individuals who are most likely to have relevant information." (*Id.* at 14-15.) The Court also invited the parties to "file a Second Joint Discovery Submission outlining the remaining issues" within three weeks from the date of the May 8 Order. (*Id.* at 17)

#### C. The Parties' Second Joint Submission

The parties filed their SJS on June 1 (Dkt. 223). With respect to identification of individuals, Plaintiffs asserted that Genentech had yet to "provide organizational charts, employee titles, or any information that would help Plaintiffs narrow their search to the relevant persons or positions in the organization." (Dkt. 223 at 2.) For its part, Genentech objected that Plaintiffs were attempting to expand the scope of the May 8 Order by demanding the identification of *every* current and former employee that had *ever* "work[ed] with Herceptin." (Dkt. 223 at 4.) Genentech reported that it was in the process of identifying current and former employees consistent with the May 8 Order, and was focusing (as instructed by the Court) on those "who are most likely to have relevant information." (*Id.* at 7.) Genentech also informed

the Court that it was concentrating on Plaintiffs' preferred time period (1996-2001) for the purpose of identifying former employees most likely to have relevant information. (*Id.* at 7-8.)

The dispute over Genentech's identification of individuals as described in the SJS appeared to be based primarily on Plaintiffs' dissatisfaction with the pace at which Genentech had identified current and former employees most likely to have relevant information concerning the subjects of Interrogatory Nos. 2(c), 2(d), 10, and 11. (*Id.* at 8-9). Plaintiffs argued that to speed up that pace, Genentech should be ordered to identify the 50 or so individuals mentioned by Genentech's counsel in an August 2016 hearing as those who "may have substantive knowledge." (Dkt. 223 at 8-9.) And they argued that in light of Genentech's alleged "delay in providing the compelled list of individuals," a deadline should be established for Genentech to identify current employees and two former employees who are likely to have "any relevant information" or "substantive knowledge." (*See id.* at 10, 29)

Genentech's position, as stated in the SJS, was that it was actively in the process of responding to the interrogatories in the manner directed in the May 8 Order. Genentech explained that it had identified ten current employees most likely to have relevant information with respect to Interrogatory Nos. 2(c), 10, and 11 even before September of 2016, and that since the May 8 Order it had been able to identify five more. (*Id.* at 10.) With respect to Interrogatory No. 2(d), Genentech explained in the SJS that despite a reasonable search and inquiry, it had thus far been unable to identify *any* current employees likely to have relevant information about the FDA's initial approval of the Herceptin BLA nearly two decades earlier. (*Id.* at n.12.)

As for former employees, Genentech argued in the SJS that since the May 8 Order had required it to identify just two former employees most likely to have relevant information with respect to the subject matter of each interrogatory, identification of all 50 individuals mentioned

by Genentech's counsel in August 2016 as those who "may have substantive knowledge" would effectively introduce far more former employees than required by the May 8 Order. Moreover, Genentech was concerned that identification of those 25 or so former employees (approximately half of the 50 individuals were former employees) might overstate their value as potential witnesses because the former employees had not yet been confirmed to be persons "most likely to have relevant information" concerning the interrogatories at issue as required by the May 8 Order. (See Id. at 11.)

#### D. The June 16 Order

The June 16 Order concluded that Genentech had, at least as of June 1, "failed to provide documents or answer interrogatories regarding (1) its internal structure, or (2) the job titles of individuals involved in the manufacturing<sup>2</sup> and labeling of Herceptin at relevant times." The Court further noted that as of that date, Genentech had not yet provided the name of even one former employee. (Dkt. 227 at 1.) It ordered Genentech to:

- "produce any organizational charts from 1997 through the present for all divisions, departments, or organizational units related to the production and/or labeling of Herceptin, including names and job titles;" and
- comply with Plaintiffs' request to "identify all current employees and two former employees with substantive knowledge, including all 50 individuals identified in August 2016;" and "in addition to identifying the two former employees most likely to have relevant information regarding each of the four categories set forth at page 10 of the SJS [referring to the categories first described in Interrogatory Nos. 2(c), 2(d), 10, and 11]," "identify the approximately fifty employees (current and former) referenced by Defendant's counsel at the August 26, 2016 hearing."

<sup>&</sup>lt;sup>2</sup> Genentech respectfully notes that notwithstanding the language of the June 16 Order, the "manufacturing... of Herceptin" had never been the subject of any of the Phase I Interrogatory for which Genentech had been ordered to identify persons most likely to have relevant knowledge.

(*Id.* at 1-2). The Court further specified that the answers or documents described above should be produced as soon as possible, but not later than 20 days from the date of the Order. It also directed that "[i]f Defendant [was] unable to produce *any* of the above," Genentech was to "file an affidavit with the Court explaining what efforts were made to comply" no later than 20 days from the date of the Order. (*Id.* at 2).

## E. The Present Motion to Compel

The present motion, which purports to seek to compel Genentech's compliance with the June 16 Order, requests an Order requiring Genentech to:

- Identify "all current employees . . . with substantive knowledge" of the subject areas identified in Plaintiffs' Interrogatory Nos. 2(c), 2(d), 10, and 11;
- Identify two former employees most likely to have relevant information regarding the subject matter in Interrogatory 11, and
- Submit an affidavit describing the steps it has taken to identify "individuals with substantive knowledge."

 $(Dkt. 233 at 9.)^3$ 

#### II. ARGUMENT

Plaintiffs' motion to compel should be denied for the simple reason that Genentech *has* timely complied with the June 16 Order.

## A. Genentech Identified Current Employees as Required

Genentech has identified 15 current employees it determined were most likely to have relevant information regarding the subject areas of Interrogatory Nos. 2(c), 10, and 11. As for the subject area of Interrogatory No. 2(d), Genentech previously explained in the SJS that it had so far been unable to identify *any* current employees likely to have relevant information about

<sup>&</sup>lt;sup>3</sup> Notably, Plaintiffs do not take issue with Genentech's compliance with other portions of the June 16 Order, including those requiring Genentech to identify the more than 50 employees referenced by Genentech's counsel at the August 26, 2016 hearing and to produce organizational charts. Genentech has now done both.

the FDA's initial approval of Herceptin (an event that occurred nearly two decades ago), but that it had identified current employees most likely to have information regarding subsequent FDA approvals relating to Herceptin, its label, and its prescribing information.<sup>4</sup>

Plaintiffs' dissatisfaction with Genentech's identification of current employees appears to arise from their expectation for the *number* of employees Genentech would identify. But that expectation is based on Plaintiffs' original formulation of their Interrogatories, and not the modified (narrowed) scope established by the May 8 Order. As described at Section I.B., *supra*, the May 8 Order expressly *rejected* the language of Plaintiffs' original interrogatories insofar as they sought identification of *all* (or every) person with knowledge of the subject matter of each interrogatory. The Court instead ordered Genentech identify (or to make efforts to identify) only the **persons who are most likely to have relevant information** (*see* Section I.B, *id.*, quoting the May 8 Order (Dkt. 207) at 14).

Genentech has done what the Court ordered. Its careful identification of those most likely to have relevant information has relieved Plaintiffs of the burden of sifting through mountains of information or taking countless depositions to arrive at the same point.<sup>5</sup> Yet despite Plaintiffs' stated goal of *narrowing* preemption-related discovery, in their present motion seeking to enforce the June 16 Order, Plaintiffs now complain that Genentech's identification of

<sup>&</sup>lt;sup>4</sup> Genentech has identified the following current employees in response to Interrogatory Nos. 2(c), 2(d) and 10: Ehab Taqiedden, Dhushy Thambipillai, Vickie Frydenlund, Alissa Goodale, Larry Davenport, Krista Terry, and Allison Guy. It has identified the following current employees in response to Interrogatory No. 11: Toshiro Carcelen, Hung-Wei-Chih, Raquel Iverson, Xanthe Lam, Karina Padilla, Dana Swisher, Camellia Zamiri, and Janet Yang.

<sup>&</sup>lt;sup>5</sup> Simply assembling a comprehensive list of hundreds (or thousands) of employee names does nothing to clarify a specific employee's level of involvement or knowledge, much less whether that employee's knowledge is duplicative. Moving discovery forward would still require assessing which of the employees identified would be most likely to have relevant information.

current employees most likely to have relevant information is not compliant simply because the list of such employees turns out to be not as *lengthy* as Plaintiffs expected it to be (*see* Dkt. 233).

Plaintiffs argue that Genentech should now be compelled to identify "all current employees . . . with substantive knowledge"—not merely those most likely to have relevant information. (Dkt. 233 at 5.) But in so doing, Plaintiffs are asking for the Court to impose a standard the Court likely never intended. The phrase "with substantive knowledge" was not used in the interrogatories at issue. Nor was it used in the May 8 Order that defined the scope of Genentech's obligation with respect to those interrogatories. The phrase was coined by Plaintiffs in the SJS (as one of two inconsistent standards suggested), and was suggested only in their final request for relief. (See Section I.C., quoting Dkt. 223 at 29).

Although the Court did refer to the phrase "with substantive knowledge" in the June 16 Order, the mere mention does not appear to represent a repudiation of the previously-established requirement that Genentech "identify all current employees and the two former employees who are most likely to have relevant information." The Court gave no affirmative indication in the June 16 Order that its intention was to abandon or replace the "most likely to have relevant knowledge" standard it had imposed (five times in the span of a single page) in the May 8 Order, as opposed to ordering compliance with that Order within 20 days. (See Dkt. No. 207 at 14-15.) In fact, the phrase "with substantive knowledge" appears in the June 16 Order only within a quotation of Plaintiffs' request. But following that very reference, and in the same paragraph, the Court again refers to Genentech's obligation to identify former employees "most likely to have relevant information."

Thus, the Court appears to use "with substantive knowledge" (Plaintiffs' phrase) and "most likely to have relevant information" (the Court's own phrase) synonymously. Yet with

their motion, Plaintiffs effectively ask the Court to apply the June 16 Order in a way inconsistent with the May 8 Order. Genentech believes the June 16 Order must be read in conjunction with the May 8 Order. Genentech reasonably believed the two Orders should be read as consistent with each other absent some evidence of a contrary intent on the part of the Court. Moreover, Plaintiffs' insistence now that Genentech must identify *all* current and former employees with "substantive knowledge" would force a dramatic expansion of the list of employees Genentech identifies. Such a result would not only be contrary to the direction established by the May 8 Order, but also contrary to Plaintiffs' stated goal of narrowing the discovery required to respond to Genentech's summary judgment motion.

Expanding the list of current and former employees to be identified by Genentech will only complicate the parties' efforts given the deadline for the completion of discovery less than two months away. Depositions of the already-identified current and former employees most likely to have relevant information are getting underway next week (August 3 and 4), and Genentech expects to be able to timely produce custodial files for those witnesses. But that said, Plaintiffs have already expressed to Genentech a concern about being able to complete their Phase I discovery by the September 22 deadline.<sup>6</sup> If hundreds of additional potential witnesses are now to be identified, a schedule extension will probably be necessary.

Genentech respectfully requests that Plaintiffs' request that the Court compel compliance with this alternative standard for "all current employees . . . with substantive knowledge" be rejected.

<sup>&</sup>lt;sup>6</sup> Genentech would be amenable to (and has offered Plaintiffs) a sixty-day extension of the present discovery deadline, though it reserves its right to object to any depositions that would exceed the number permitted by Fed. R. Civ. P. 30(a)(1).

#### B. Genentech Identified Former Employees as Required.

Genentech previously identified four former employees it determined were most likely to have relevant information regarding the subject areas of Interrogatory Nos. 2(c), 2(d), and 10.<sup>7</sup> With respect to Interrogatory No. 11, Genentech previously explained to Plaintiffs that its research revealed that two long-time *current* employees who were working on Herceptin 20 years ago<sup>8</sup> were those most likely to have relevant information between 1996-2001, the time frame Plaintiffs told Genentech they were most interested in. (*See* July 5 correspondence from Alicia Donahue to David Keglovits and Matthew Sill, attached here as Exhibit 1.)

Presumably, the Court had directed the identification of former employees in the May 8 Order in recognition of the likelihood that persons who were employees from 1996-2001 are generally less likely to be current Genentech employees. But in this instance, that was not the case, and because the two employees Genentech has identified as those most likely to have relevant information are still current employees, it is inherently reasonable to identify them rather than searching further to try to identify less knowledgeable former employees.

Plaintiffs' contention that Genentech has not identified two former employees in connection with Interrogatory No. 11 elevates form over substance. Moreover, Plaintiffs never raised an issue related to Genentech's response to Interrogatory No. 11 in their July 11 letter, and subsequently confirmed that they had no issues beyond that letter. It is therefore unclear to Genentech why Plaintiffs have moved to compel on this point.

<sup>&</sup>lt;sup>7</sup> Genentech has identified the following former employees in response to Interrogatory No. 2(c): Melissa Brammer and Robert Garnick. It has identified the following former employees in response to Interrogatory No. 2(d): Karl Trass and Robert Garnick. It has identified the following former employees in response to Interrogatory No. 10: Cheryl Madsen and Robert Garnick.

<sup>&</sup>lt;sup>8</sup> Xanthe Lam and Janet Yang.

## C. No Affidavit Was Required of Genentech.

As for Plaintiffs' claim that Genentech violated the June 16 Order by not filing an affidavit, no such affidavit was required or necessary. The June 16 Order indicates that an affidavit was required only "[i]f Defendant is unable to produce *any* of the above"—referring to organizational charts, identification of current and former employees with substantive knowledge, and the approximately 50 employees (current and former) mentioned by counsel in August 2016. (Dkt No. 227 at 2.) Genentech *did* produce all of that information, and so no affidavit was required.

## D. No Order to Compel or Sanctions Are Warranted

Even if the Court were to determine that Genentech was incorrect to presume that the phrase "with substantive knowledge" used in the June 16 Order represented the functional equivalent of "most likely to have relevant information" for purposes of identifying current employees in response to Plaintiffs' Interrogatory Nos. 2(c), 2(d), 10 and 11, there is no basis for sanctions. Sanctions under Rule 37(b)(2)(C) are only permitted if the purported discovery omission was not "substantially justified." *See id.; see also Sun River Energy, Inc. v. Nelson*, 800 F.3d 1219, 1224 (10th Cir. 2015). Here, given the history of this issue and the clear standard established by the May 8 Order that preceded the June 16 Order, Genentech's interpretation was "substantially justified." Moreover, Genentech made its employee identifications and complied with the other aspects of the June 16 Order within the prescribed time. Because Genentech acted reasonably and in good faith, discovery sanctions are not warranted here.

<sup>&</sup>lt;sup>9</sup> For reasons discussed above at Sections II.A and B, Genentech reasonably believed that its identification of current and former employees most likely to have relevant knowledge satisfied this requirement.

#### CONCLUSION

For all the foregoing reasons, Genentech respectfully requests that Plaintiffs' motion to compel (Dkt. 233) be denied in its entirety. Genentech notes that the parties continue to meet and confer on a weekly basis to address not only new and existing discovery differences, but also deposition scheduling and other issues as they arise. It is Genentech's sincerest hope that this ongoing procedure and the cooperation it requires will serve to facilitate Plaintiffs' remaining Phase I discovery and minimize the need for Court involvement in discovery matters on a going forward basis.

Respectfully submitted,

/s/ William W. O'Connor

WILLIAM W. O'CONNOR, OBA No. #13200

Newton, O'Connor, Turner & Ketchum, PC

15 W. 6th Street, Suite 2700

Tulsa, OK 74119

Telephone: (918) 587-0101

Facsimile: (918) 587-0102

Email: boconnor@newtonoconnor.com

-and-

ALICIA J. DONAHUE, Bar No. 117412

(admitted pro hac vice)

SHOOK, HARDY & BACON LLP

One Montgomery, Suite 2700

San Francisco, CA 94104

Telephone: (415) 544-1900

Facsimile: (415) 391-0281

Email: adonahue@shb.com

JAMES P. MUEHLBERGER, Bar No. 51346

(admitted pro hac vice)

SHOOK, HARDY & BACON LLP

2555 Grand Blvd.

Kansas City, MO 64108

Telephone: (816) 474-6550

Facsimile: (816) 421-5547

Email: jmuehlberger@shb.com

Attorneys for Defendant Genentech, Inc.

## **CERTIFICATE OF SERVICE**

I hereby certify that on the 26th day of July, 2017, the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ William W. O'Connor William W. O'Connor